



MEDIONICS INTERNATIONAL INC.

114 ANDERSON AVENUE, MARKHAM, ONTARIO, CANADA L6E 1A5 . TEL. (905) 472-6544 • FAX (905) 472-6549

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U.S. Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 106 I,
Rockville, Maryland 20852
U.S.A.

September 29, 1999

Dear Sir / Madam:

Re: Docket Number 98N- 12 15
Foreign Establishment Registration and Listing

Medionics International Inc. is a small Canadian manufacturer exporting peritoneal dialysis equipment and accessories to United States since 1976. We are registered with FDA under registration number 9611088.

We would like to bring to your attention that the above ruling adversely affects our business and would essentially kill our exports to United States.

WC believe that finding a single U.S. agent who would be qualified enough to handle all the regulatory tasks and responsibilities associated with our business and as described in the above ruling would be extremely difficult for us. Furthermore, the cost of maintaining such a credible and qualified agent would be so high that small niche companies like ours would have to essentially get out of the U.S. market.

Due to very severe market competition, our profit margins are already so low that any increase in our overhead would force us to reconsider our presence in United States. We have very successfully managed our regulatory commitments to FDA from our base in Toronto, Canada, and we have strong doubts that any person or any agent residing in United States can do an equally good or better job.

Therefore, we would request you to kindly reconsider your decision and not implement the above ruling as it would be a serious blow to the small innovative foreign companies. Thank you very much for your understanding.

Sincerely,

Mahesh Agarwal
President

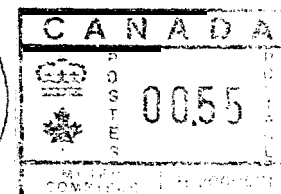
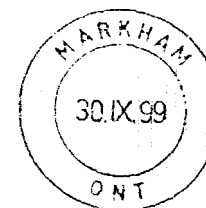
cc: Debbie Walker, Area Director US Healthcare, Ontario Government, Canada.
Ms. Birgit Mattiesen, Commercial Officer, Canadian Embassy, Washington, D.C.

98N-1215

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